Study Number:	C12013-01
Study Sex:	Male
PWG Approval Date:	See web page for date of PWG Approval
Version:	v1.7.5
Stat Version:	2025.06.02S

Male

	Treatment Groups (mg/kg)				
	0	**30**	**100**	**300**	**1000**
Disposition Summary					
Animals Initially In Study	**5**	**5**	**5**	**5**	**5**
Censored					
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	**5**	**5**	**5**	**5**	**5**
Number Animals Examined Microscopically	**5**	**5**	**5**	**5**	**5**
ALIMENTARY SYSTEM					
ESOPHAGUS	(1)	(0)	(0)	(0)	(0)
PERIESOPHAGEAL TISSUE; INFLAMMATION; GRANULOMATOUS	1 (100%)				
SUBMUCOSA; INFLAMMATION; SUPPURATIVE	1 (100%)				
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
HEMATOPOIETIC SYSTEM					
None					
HEPATOBILIARY SYSTEM					
LIVER	(5)	(5)	(5)	(5)	(5)
HEPATOCYTE; HYPERTROPHY	0	5 (100%) **	5 (100%) **	5 (100%) **	5 (100%) **

Male

	Treatment Groups (mg/kg)				
	0	**30**	**100**	**300**	**1000**
IMMUNE SYSTEM					
LYMPH NODE	(1)	(0)	(0)	(0)	(0)
AXILLARY; INFLAMMATION; SUPPURATIVE	1 (100%)				
CERVICAL; INFLAMMATION; SUPPURATIVE	1 (100%)				
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS SYSTEM					
None					
REPRODUCTIVE SYSTEM					
EPIDIDYMIS	(5)	(0)	(1)	(0)	(5)
SPERM GRANULOMA			1 (100%)		
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
KIDNEY	(5)	(5)	(5)	(5)	(5)
CHRONIC PROGRESSIVE NEPHROPATHY	3 (60%)	1 (20%)	3 (60%)	1 (20%)	2 (40%)

LEGEND

Censored animals are animals not in one of the other disposition categories that are removed prior to the end of the study. The censored animals are included in the pathology data if microscopic examination of tissues was performed.

In the rows with the tissue names, the number of animals with each tissue is shown in parentheses.

In the rows with the lesion names, the number of animals with observation are reported with percent incidence in parentheses. If none of the animals examined have the specific lesion, there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion; in that case a 0 is included for the control group on the table for that lesion.

For some animals, a tissue was examined microscopically only when a gross lesion was detected. These findings were not analyzed statistically against the control group.

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) one-sided tests.

Statistical significance for the control group indicates a significant trend test.

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group.

* Statistically significant at p <= 0.05

** Statistically significant at p <= 0.01

** END OF REPORT **